



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFD-613

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 18-716/S-022

AUG 13

GlaxoWellcome  
Attention: Ms. Elizabeth A. Nies  
Five Moore Drive  
Research Triangle Park, NC 27709

Dear Ms. Nies:

Please refer to your supplemental new drug application dated July 17, 1998 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trandate (labetalol hydrochloride) 100, 200 and 300 mg Tablets.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

This supplemental new drug application provides for final printed labeling revised as follows:

1. The following statement has been added to the CONTRAINDICATIONS section:  
  
Beta-blockers, even those with apparent cardioselectivity, should not be used in patients with a history of obstructive airway disease, including asthma.
2. The phrase, "Trandate Tablets therapy" has been changed to, "therapy with TRANDATE Tablets" throughout the text.
3. Under the PRECAUTIONS/Pediatric Use subsection, "children" has been changed to 'pediatric patients.'
4. Under the HOW SUPPLIED section, "TRANDATE 100 GLAXO," "TRANDATE 200 GLAXO," AND "TRANDATE 300 GLAXO" have been changed to "TRANDATE 100," "TRANDATE 200," and "TRANDATE 300" respectively.

Your submission stated no later than November 17, 1998 as the implementation date for the changes.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert dated June 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Ms. Zelda McDonald  
Regulatory Health Project Manager  
(301) 594-5333

Sincerely yours,

Raymond J. Lipicky, M.D.  
Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research